



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,890	09/15/2006	Massimo Prini	P48612	2374
2352 7590 12/16/2009 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403				
EXAMINER				
VU, JAKE MINH				
ART UNIT		PAPER NUMBER		
1618				
MAIL DATE		DELIVERY MODE		
12/16/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,890

Applicant(s)

PRINI, MASSIMO

Examiner

Jake M. Vu

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/226)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Receipt is acknowledged Applicant's Argument filed on 09/14/2009.

- Claim 1 has been amended.
- Claims 1-4 are pending in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, pertaining to "comprising hydroxyethylcellulose as the only gelling agent and bioadhesive agent", **is withdrawn** in view of Applicant's amendment and explanation.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, pertaining to the term "gelling agents", **is maintained** for reasons of record in the previous office action filed on 04/14/2009 and as discussed below .

Applicant argues that one having an ordinary skill in the relevant art would be well acquainted with the concept of "gelling agents" and well aware of what materials constitute such "gelling agents". The particular materials referred in the Office Action,

as discussed for example at p. 1 of the specification, are provided as non-limiting examples of gelling agents that are well-known and commonly used in the art. The Examiner finds this argument unpersuasive, because Applicant provides no list of common gelling agents, or what formula would constitute gelling agents, wherein Applicant further states that "example [such as hydroxyethylcellulose, acrylic or methacrylic acid polymers, chitosan, and polycarbophil] at p. 1 of the specification, are provided as non-limiting examples of gelling agents" provide no standard for ascertaining what is a gelling agent, and one of ordinary skill in the art would not be reasonably apprised of the scope of the term "gelling agent". Therefore, one would not know what are the metes and bounds of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 3 and 4 rejected under 35 U.S.C. 102(b) as being anticipated by ARKIN et al (US 2003/0039704) **are maintained** for reasons of record in the previous office action filed on 04/14/2009 and as discussed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 rejected under 35 U.S.C. 103(a) as being unpatentable over ARKIN et al (US 2003/0039704) **are maintained** for reasons of record in the previous office action filed on 04/14/2009 and as discussed below.

Response to Arguments

Applicant argues that the Arkin reference discloses, in examples 1-4 gel compositions comprising hydroxyethylcellulose, diethylene glycol monoethyl ether, surfactants and preservatives, but not acidifiers. The reference does mention acidifiers, but only in the context of Examples 5 and 6 which are directed to creams (not gels) comprising lactic acid. These cream compositions, however, contain no hydroxyethylcellulose, i.e., because they are not gels. Thus, the reference does not disclose compositions comprising hydroxyethylcellulose and an acidifying agent. Rather, it discloses (1) gel compositions comprising, inter alia, hydroxyethylcellulose, and (2) cream compositions comprising, inter alia, an acidifier (e.g., lactic acid). There is no teaching, however, or even a suggestion, of a composition comprising both the hydroxyethylcellulose and an acidifier. Since, therefore, the reference does not disclose

any composition including all of the claimed constituents recited in, e.g., claim 1, applicant respectfully submits that claim 1 is not anticipated by the Arkin reference.

The Examiner finds this argument unpersuasive, because ARKINI teaches additives to these compositions include components commonly using in the art of pharmaceutical and cosmetic formulary. One skilled in the art obviously knows that acidifiers, such as lactic acid, are commonly used to adjust the pH of a composition depending on the area of use, such as facial, hair or vaginal would require a different optimal pH. In addition, Applicant's specification disclosed that acidifiers are commonly used (see Specification at [0015]).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618